

Dear Healthcare Professional,

Thank you for your unsolicited request for information. Accompanying this letter is the following information you requested on ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg. If we can be of any further assistance, please contact our Medical Information department at 844-445-8843 between the hours of 9:00 AM to 8:00 PM ET (6:00 AM to 5:00 PM PT), Monday through Friday or via email at iluvienmedinfo@anipharma.com.

ILUVIEN is indicated for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.

ILUVIEN is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

ILUVIEN is contraindicated in patients with active or suspected ocular or periocular infections including most viral disease of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections and fungal diseases.

ILUVIEN is contraindicated in patients with glaucoma, who have cup to disc ratios of greater than 0.8.

ILUVIEN is contraindicated in patients with known hypersensitivity to any components of this product.

Please see the enclosed ILUVIEN Prescribing Information (PI) for detailed information including Warnings and Precautions and Adverse Reactions as well as the appropriate use of ILUVIEN.

This communication may contain confidential, proprietary, and/or privileged information. It is intended solely for the use of the addressee. If you are not the intended recipient, you are strictly prohibited from disclosing, copying, distributing or using any of this information. If you received this communication in error, please contact the sender immediately and destroy the material in its entirety, whether electronic or hard copy.

Thank you for your inquiry.

Sincerely,



Steve Wu, PharmD
ANI Pharmaceuticals Medical Information

Treatment Experience With ILUVIEN® Intravitreal Implant and Supplemental Corticosteroid Therapy, Including Dexamethasone

Abstract

- This document provides summary information pertaining to ILUVIEN® (fluocinolone acetonide [FAC] intravitreal implant) 0.19 mg in the treatment of diabetic macular edema (DME) and treatment of chronic non-infectious uveitis affecting the posterior segment of the eye (NIU-PS)
- After anti-vascular endothelial growth factor (VEGF) failure, patients with DME may be switched to an ILUVIEN implant. Patients requiring additional relief may receive add-on dexamethasone or other corticosteroid therapies
- Summarized in this document are the results of a literature search that led to published reports about add-on dexamethasone in the treatment of DME—including summaries of real-world experience, the PALADIN study, the IRISS Registry Study, and the USER chart review study
 - Data on the proportion of patients receiving additional study treatments, rescue laser treatments, or off-protocol therapies based on a subgroup analysis of the FAME studies is also included in this document

Note that this document is for information purposes only and has been sent as a professional courtesy to provide you with data to assist in making your own practicing decisions. Please refer to the ILUVIEN (fluocinolone acetonide [FAC]) implant USPI for full [Prescribing Information](#) and safety information. ANI Pharmaceuticals does not recommend the use of its products in any manner inconsistent with the FDA-approved labeling. If you have further questions, please contact the Medical Affairs Department at <drugsafety@anipharma.com>.

To report an adverse event for any ANI Pharmaceuticals product, please call 1-800-308-6755 or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Email: <drugsafety@anipharma.com>

Introduction

Clinical Background

ILUVIEN is indicated for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (IOP).¹

ILUVIEN is indicated the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.¹

Composition of ILUVIEN

ILUVIEN is a non-bioerodable intravitreal implant in a drug delivery system containing 0.19 mg FAc, designed to release ILUVIEN at an initial rate of 0.25 µg/day and lasting 36 months. Each ILUVIEN consists of a light brown 3.5mm x 0.37mm implant containing 0.19 mg of the active ingredient FAc and the following inactive ingredients: polyimide tube, polyvinyl alcohol, silicone adhesive, and water for injection.¹

Pharmacokinetics

In a human pharmacokinetic study of ILUVIEN, FAc concentrations in plasma were below the lower limit of quantitation of the assay (100 pg/mL) at all post-administration time points from Day 7 through Month 36 following intravitreal administration of a 0.2 mcg/day or 0.5 mcg/day ILUVIEN insert.¹

Clinical Pharmacology

ILUVIEN contains the corticosteroid FAc. Corticosteroids inhibit inflammatory responses to a variety of inciting agents including multiple inflammatory cytokines. They inhibit edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. Corticosteroids are thought to act by inhibition of phospholipase A₂ via induction of inhibitory proteins collectively called lipocortins. It is postulated that these proteins control biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting release of the common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A₂.¹

Warnings and Precautions

Intravitreal Injection-related Effects

Intravitreal injections, including those with ILUVIEN, have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments. For patients with non-infectious uveitis affecting the posterior segment, hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection [see Patient Counseling Information (17)]. Patients may experience temporary blurred vision after injection of the implant.¹

Intraocular Pressure (IOP) Increase

Prolonged use of corticosteroids may result in the development of glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be routinely monitored during the course of the treatment.¹

Cataracts

The use of corticosteroids may result in posterior subcapsular cataract formation.¹

Delayed Corneal Wound Healing

The use of corticosteroids after cataract surgery may delay healing and increase the incidence of bleb formation.¹

Corneal and Scleral Melting

Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of ophthalmic corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation of the globe.¹

Bacterial Infections

Prolonged use of corticosteroids may suppress the host immune response and thus increase the hazard of secondary ocular infections. Acute purulent or parasitic infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication. If signs and symptoms fail to improve after 2 days, the patient should be reevaluated.¹

Viral Infections

Use of ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended.¹

Fungal Infections

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid application. Fungus invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate.¹

Risk of Implant Migration

Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.¹

The registered FAME A and B trials occurred prior to the market approval of the OZURDEX® (dexamethasone intravitreal implant).¹ As a result, there are no data available on supplementation with OZURDEX from the pivotal registration studies. Post-marketing data on ILUVIEN and supplemental therapy are summarized below.

Pivotal ILUVIEN Studies and Supplementary Treatment

FAME Studies

FAME A and FAME B were two phase 3, multicenter, randomized, double-masked, sham injection-controlled studies conducted over 36 months.² The objective of the FAME studies was to assess the long-term efficacy and safety of ILUVIEN in patients with DME despite prior macular laser treatment.²

When the FAME studies were established, anti-VEGF therapies were not approved for DME. While these were not allowed as rescue treatments throughout the duration of the study, they could have been used as off-protocol treatment at the investigator’s discretion. A lower percentage of patients treated with ILUVIEN required supplemental therapy (28 patients, 13.4%) vs sham (39 patients, 34.8%). Of these patients, 7 (3.3%) treated with ILUVIEN and 17 (15.2%) treated with sham, respectively, received supplemental anti-VEGF therapy while enrolled in the FAME studies.

FAME Studies Subgroup Analysis

Cunha-Vaz and colleagues conducted a preplanned subgroup analysis of chronic (≥3 years diagnosis) vs nonchronic (<3 years) DME in patients from the FAME studies.^{2,3} One of the outcomes included in this post-hoc analysis included the proportion of patients receiving additional study treatments, rescue laser treatments, or off-protocol therapies within each treatment group for chronic vs nonchronic DME.³

Among patients with nonchronic DME, 13.9% in the sham group and 3.0% in the ILUVIEN group received off-protocol anti-VEGF treatments ($P=0.002$) (Table 1).³ In patients with chronic DME, 15.2% of the sham group and 3.3% of the ILUVIEN group required anti-VEGF therapies ($P<0.001$). Intravitreal triamcinolone acetonide (IVTA) usage was 15.3% in the nonchronic sham group vs 7.2% in the ILUVIEN group ($P=0.057$) and 24.1% in the chronic sham group compared to 8.1% in the ILUVIEN group ($P<0.001$) (Table 1).³ These findings demonstrated a significant reduction in the need for additional anti-VEGF and corticosteroid treatments among patients receiving ILUVIEN implants, particularly in patients with chronic DME, supporting the efficacy of ILUVIEN implants in reducing the frequency of supplementary therapies.³

	Nonchronic DME (<3 Years)		Chronic DME (≥3 Years)	
	Sham (n=72)	ILUVIEN (n=166)	Sham (n=112)	ILUVIEN (n=209)
Study treatments (sham injection or ILUVIEN), %				
1 treatment	80.6	72.7	66.1	76.1
2 treatments	16.7	24.8	27.7	18.7

≥3 treatments	2.8	2.4	6.3	5.3
Rescue laser treatments (at masked physician's discretion after Week 6)				
Patients, n (%)	45 (62.5)	71 (42.8)	69 (61.6)	85 (40.7)
<i>P</i> -value	0.136		0.003	
Off-protocol treatments				
Any, n (%)	22 (30.6)	29 (17.5)	39 (34.8)	28 (13.4)
<i>P</i> -value	0.023		<0.001	
IVTA, n (%)	11 (15.3)	12 (7.2)	27 (24.1)	17 (8.1)
<i>P</i> -value	0.057		<0.001	
Anti-VEGF, n (%)	10 (13.9)	5 (3.0)	17 (15.2)	7 (3.3)
<i>P</i> -value	0.002		<0.001	

Table 1. Study Treatments, Laser Treatments, and Off-Protocol Treatments Through Month 36 in Patients With Chronic and Nonchronic Diabetic Macular Edema

IVTA, intravitreal triamcinolone acetonide; VEGF, vascular endothelial growth factor.

USER Study (Real-World IOP Data)

The USER Study was a retrospective chart review evaluating the anatomical, functional, and IOP responses to DME treatments pre- and post-ILUVIEN implantation compared with baseline 3 years prior to ILUVIEN administration.⁴ This chart review included 160 eyes from 130 patients across four different U.S. centers.⁴ Patients were required to have received ILUVIEN for the treatment of DME in at least one eye before January 1, 2016.⁴ DME treatments administered up to 36 months pre-ILUVIEN implant and up to 24 months post-ILUVIEN implant were recorded, and treatment frequency was calculated. Limitations of this study included retrospective data analysis and lack of a comparator arm.⁴

Post-ILUVIEN administration, visual acuity was maintained at pre-ILUVIEN levels with fewer injections (Figure 1).⁴ Pre-ILUVIEN implant patients received one treatment every 2.9 months compared to post-ILUVIEN administration, where patients received one supplemental treatment every 14.3 months ($P < 0.001$).⁴ There were 63% of eyes that did not require any supplemental DME treatments for up to 24 months post-ILUVIEN implant.⁴ Only 14.9% of the 60 patients needing additional DME therapy received intravitreal steroids.⁴

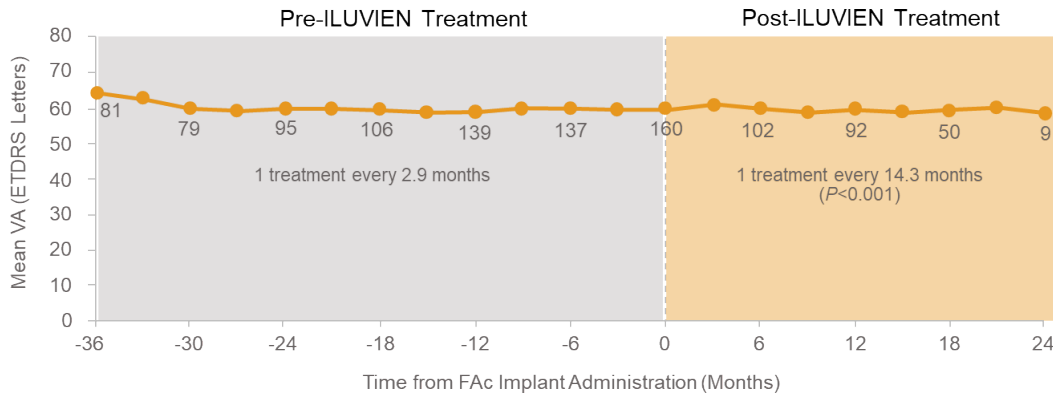


Figure 1. Visual Acuity and Treatment Frequency Pre- and Post-ILUVIEN Administration

In a subgroup of patients with the baseline best corrected visual acuity (BCVA) ($\geq 20/40$), the frequency of treatment was prolonged from once every 2.9 months pre-ILUVIEN administration to once every 22 months post-ILUVIEN administration (Figure 2).⁴ In the subgroup with baseline vision of 20/40 to 20/100, treatment frequency decreased from once every 3.2 months pre-ILUVIEN to every 15.2 months post-ILUVIEN implant in eyes with 20/40 or better and 20/100 to <20/40 vision, respectively ($P<0.001$ for reductions in both subgroup comparisons) (Figure 2).⁴

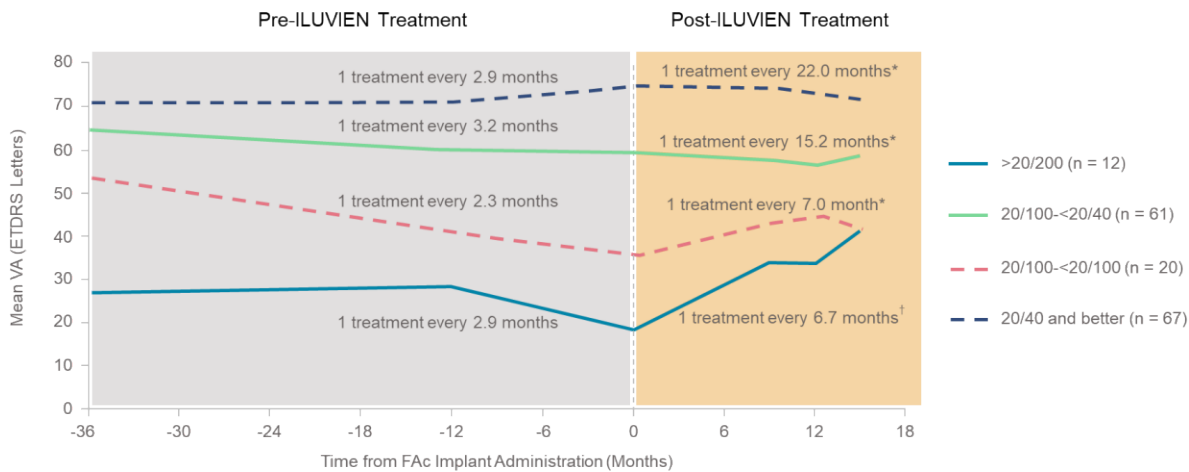


Figure 2. Patient Visual Acuity (VA) and Treatment Frequency by Baseline VA

*Indicates significant difference in VA between pre- and post-0.2 lg/day FAc implant administration at $P<0.001$; †Significant difference in VA between pre- and post-0.2 lg/day FAc implant administration at $P=0.026$.

PALADIN (Post-Marketing Observational Study)

The PALADIN Study was a 3-year, postmarketing, open-label, observational study assessing the long-term safety and efficacy of the ILUVIEN implant in patients with DME who had previously received ocular corticosteroids without a clinically significant rise in IOP.⁵ This study included 202 eyes from 159 patients and evaluated the safety, visual, anatomical, and treatment burden- related outcomes for up to 36 months. Retrospective collection of up to 36 months of data for prior IOP, BCVA, and central

subfield thickness (CST) allowed for comparisons of pre-ILUVIEN and post-ILUVIEN outcomes.⁵At the end of the 36-month study period, 94 out of 202 eyes completed the study. The most common reason for leaving the study (32.4%) was due to the protocol requiring fellow eyes to be discontinued once the study eye completed 36 months, withdrawal of consent (23.14%), unknown reason (12.96%), death (6.48%), adverse events (1.85%), protocol violations (1.85%), and unsatisfactory therapeutic benefit (0.92%).⁵

In the all-eyes population (n=202 eyes), there was a 70.5% reduction in the median number of treatments needed for DME per year from 3.4 treatments pre-ILUVIEN implant to 1.0 treatment post-ILUVIEN implant (Figure 3).⁵ 13.4% of patients post-ILUVIEN implant requiring additional DME treatment received a dexamethasone implant.⁵ Of the total number of eyes completing 36 months of follow-up, 25.53% remained rescue treatment free.⁵

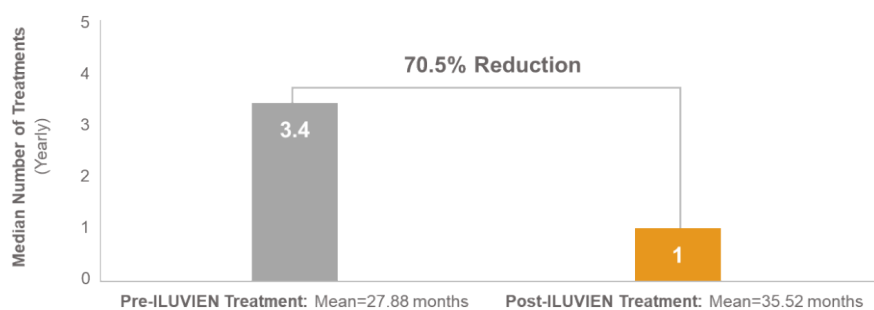


Figure 3. Median Number of Treatments Per Year Pre- vs Post-ILUVIEN Treatment

The majority of eyes received some type of anti-VEGF and/or steroid therapy pre-ILUVIEN implant.⁶ The most common anti-VEGF treatment pre-ILUVIEN was bevacizumab (58.4%), and the most common steroid was OZURDEX (70.3%).⁶ Post-ILUVIEN administration, the percentage of eyes requiring supplemental therapy for each of the following therapies significantly reduced: 55% reduction in laser therapy, 36% reduction in anti-VEGF therapy, and 78% reduction in steroid treatment ($P<0.0001$) (Table 2; Figure 4).⁶

	Before ILUVIEN		After ILUVIEN		Percent Change After ILUVIEN (<i>P</i> -Value)	
	Total Events	% Eyes	Total Events	% Eyes	Total Events	% Eyes
Mean follow-up time (months)	27.9		27.6			
Laser (total)	168	42.6	75	19.3	-55 (<0.0001)	-55 (<0.0001)
Focal	81	24.8	35	12.9	-57 (0.0009)	-48 (0.0011)
Grid	21	8.9	13	3.0	-38 (0.1364)	-66 (0.0073)

PRP	66	25.2	27	6.9	-59 (<0.0001)	-73 (<0.0001)
Anti-VEGF (total)	1038	82.2	736	53.0	-32 (<0.0001)	-36 (<0.0001)
Pegaptanib	6	1.0	0	0.0	-100 (N/A)	-100 (N/A)
Bevacizumab	448	58.4	415	33.2	-7 (0.0316)	-43 (<0.0001)
Ranibizumab	387	29.7	103	8.9	-73 (<0.0001)	-70 (<0.0001)
Aflibercept	197	21.8	218	23.3	+11 (0.7714)	+7 (0.6803)
Steroid (total)	482	93.1	81	20.8	-83 (0.4495)	-78 (<0.0001)
Dexamethasone implant	253	70.3	54	13.4	-79 (<0.0001)	-81 (<0.0001)
IVTA (Kenalog)	13	4.5	5	1.0	-62 (0.0339)	-78 (0.0196)
IVTA (Triesence)	11	4.5	10	3.0	-9 (0.2417)	-33 (0.4386)
Ocular steroids*	200	37.1	0	0.0	-100 (N/A)	-100 (N/A)

Table 2. Treatment Events Were Significantly Reduced After ILUVIEN Implantation, All Eyes (n=202)

*Undisclosed ocular steroid treatments.

mo, month; IVTA, intravitreal triamcinolone acetonide; PRP, panretinal photocoagulation; VEGF, vascular endothelial growth factor.

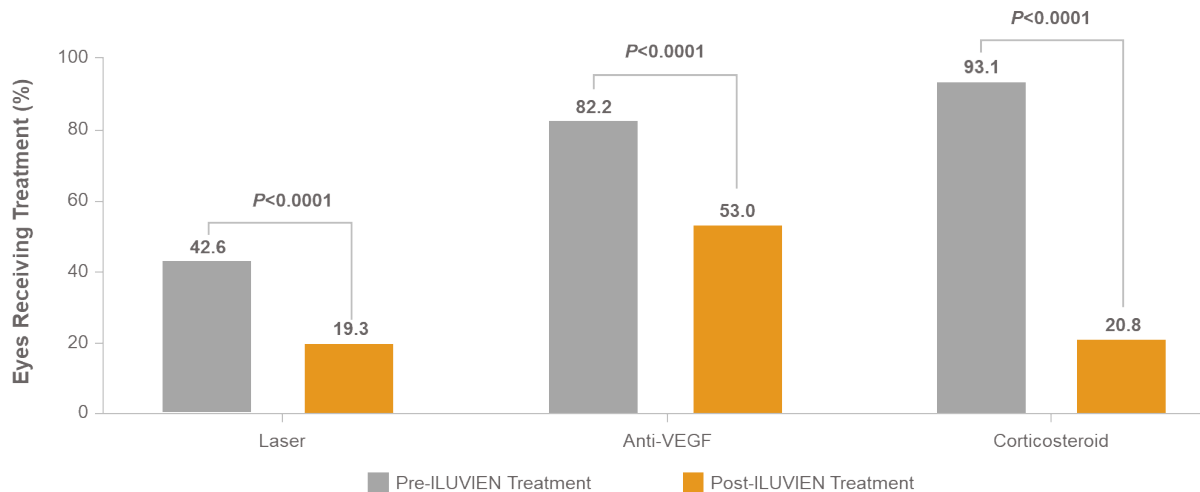


Figure 4. Percentages of Eyes Receiving Laser, Anti-VEGF, or Corticosteroid Treatment During the 36 Months Pre- and Post-ILUVIEN Treatment

VEGF, vascular endothelial growth factor.

IRISS Registry Study: Effects of Add-on Corticosteroid on Intraocular Pressure

The ILUVIEN Registry Safety Study (IRISS) was a multi-center, open-label, observational study collecting real-world data on the safety and effectiveness of ILUVIEN (FAc) in 695 eyes from 556 patients, 96.7% (672 patients) of whom had a diagnosis of DME.⁷ The mean follow-up time was 37.8 months.⁷

A total of 56.3% of ILUVIEN-treated eyes received no additional treatments during the 36 months of follow-up post-ILUVIEN administration.⁷ Mean time to any supplementary treatment was 350.2 days and the mean time from first to second supplementary treatment was 92.1 days.⁷ Intravitreal anti-VEGF supplementation occurred in 24.3% of eyes with a mean time to supplementation of 393.0 days.⁷ Steroid supplementation occurred in 10.6% of eyes with a mean time to supplementary steroid of 377.0 days.⁷ During the 36-month period of follow-up, the majority (44.11%) of additional therapies were given in Year 2, followed by Year 1 (35.6%), and Year 3 (20.3%).⁷

Effects on Intraocular Pressure: A Retrospective Chart Review

Gonzalez and colleagues reported a real-world analysis of IOP response in eyes treated with ILUVIEN that received supplemental ocular steroid injection for DME.⁸ In this retrospective chart review, 65 eyes were identified from chart reviews, totaling 337 eyes that had received at least one supplemental ocular steroid injection after ILUVIEN implantation.⁸ Supplemental steroid injections included dexamethasone (79%), triamcinolone acetonide (13%), and ILUVIEN (8%). Mean follow-up time was 671 days (range, 162–1265 days).⁸ Mean time to first supplemental steroid was 273 days post-ILUVIEN implant.⁸ Two patients had an IOP >30 mmHg after supplemental steroid administration, and a single case underwent incisional surgery.⁸ Few eyes experienced an IOP >25 mmHg post-ILUVIEN despite the supplemental steroid injections administered (Figure 5).⁸

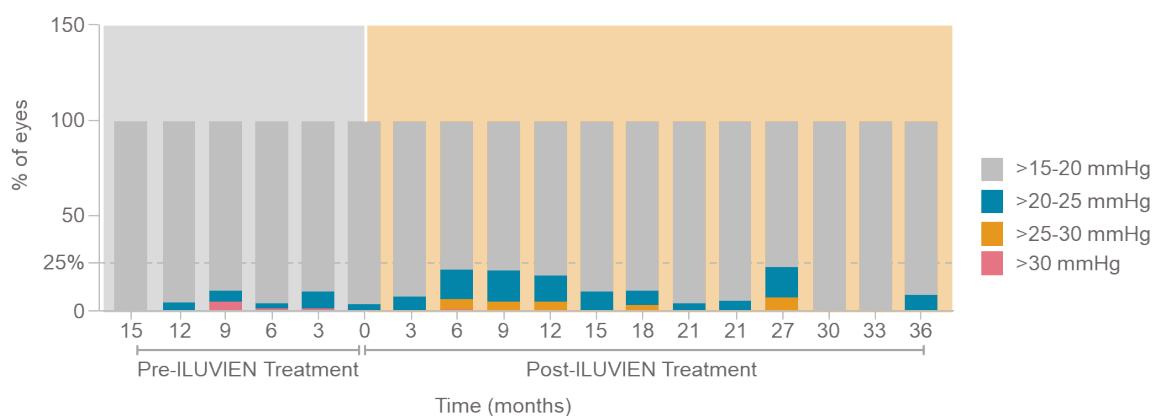


Figure 5. Absolute IOP Over Time

Overall, the mean IOP change was <3 mmHg over the follow-up period in eyes with up to 3 or more additional steroids (Figure 6).⁸ Of the 45 eyes that received one supplemental steroid post-ILUVIEN

administration, the mean IOP increase was 2 mmHg.⁸ Of those eyes that received 2 supplemental steroids, the mean IOP increase was 2 mmHg.⁸ Of the eyes that received 3 supplemental steroids, the mean IOP increase was 2.5 mmHg.⁸ Results suggest that the steroid challenge is predictive of IOP response post-ILUVIEN administration, even in the limited set of eyes that required supplemental intraocular steroid.⁸

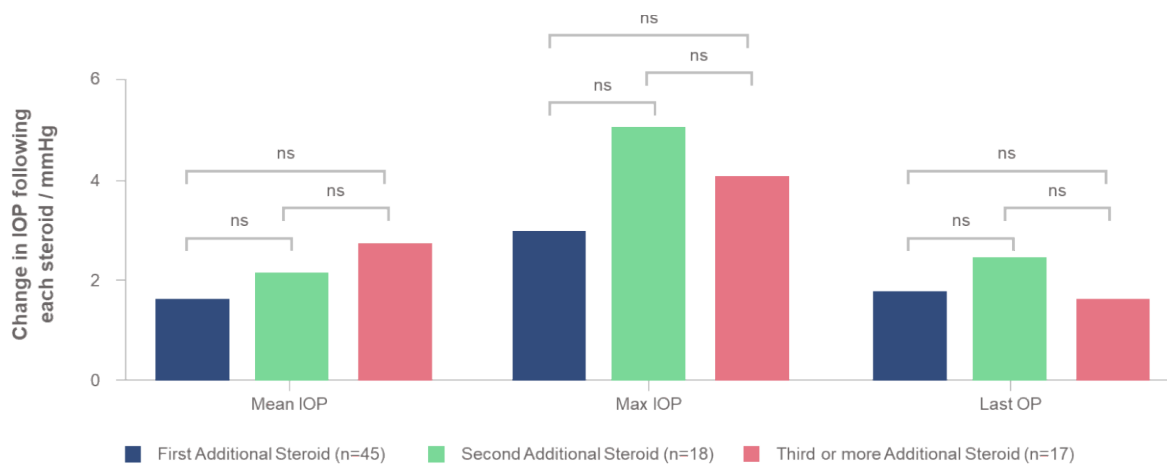


Figure 6. Mean, Max, and Last IOP After Additional Steroid

A Retrospective Chart Review of Patients With DME Switching to ILUVIEN

Rehak and colleagues published a retrospective, single-center chart review from Germany of outcomes in patients with DME who switched directly from an anti-VEGF to an ILUVIEN implant or indirectly after a trial of dexamethasone after anti-VEGF therapy failure.⁹ Among 49 eyes, patients were assigned to Group A (those who switched to ILUVIEN after anti-VEGF therapy) or Group B (those who switched to dexamethasone and then to ILUVIEN after >4 months).⁹ Among the patients in Group B, 100% had received an average of 1.27 dexamethasone implants prior to the study. The average duration of treatment with dexamethasone was 6.5 months (standard deviation [SD] 2.7).⁹

Nine patients (37.5%) in Group A received additional intravitreal DME therapy after ILUVIEN implantation.⁹ These included dexamethasone implants (mean 1.7 ± 1.0 treatments) in 3 patients (12.5%), additional anti-VEGF injections (mean 2.2 ± 0.8) in 4 patients (16.7%), an additional ILUVIEN implant (24 months after first implant) in 1 patient (4.2%), and dexamethasone combined with anti-VEGF injections in 1 patient (4.2%).⁹ In Group B, there were also 9 patients (36.0%) who received additional DME therapy.⁹ These included additional dexamethasone (mean 1.6 ± 0.7 treatments) in 8 patients (32.0%) and an additional dexamethasone implant plus two anti-VEGF injections in 1 patient (4.0%).⁹

The mean duration of treatment was 22.7 ± 13.9 months in Group A and 21.8 ± 9.6 months in Group B.⁹ After ILUVIEN monotherapy, mean BCVA was 65.7 Early Treatment of Diabetic Retinopathy Study (ETDRS) letters in Group A and 67.3 letters in Group B, representing increases of 7.4 letters and 3.2 letters in Groups A and B, respectively.⁹ Mean central macular thickness (CMT) after ILUVIEN monotherapy had decreased to $456.0 \mu\text{m}$ (-147.7) in Group A and $400.6 \mu\text{m}$ (-169.0) in Group B.⁹

Fourteen patients (28.5%; 9 from Group A and 5 from Group B) experienced an increase in IOP >21 mmHg following ILUVIEN treatment.⁹ In 13 eyes (26.5%; 6 eyes from Group A and 7 eyes from Group B), IOP rose >10 mmHg compared to baseline levels.⁹ All cases were effectively managed with IOP-lowering drops, without the need for surgical intervention.⁹ Cataract progression occurred in 73.1% (19 out of 26) of phakic eyes after ILUVIEN implantation. During follow-up, 26.9% of phakic eyes (n=7; 2 in Group A and 5 in Group B) underwent phacoemulsification.⁹

References

1. ILUVIEN (fluocinolone acetonide intravitreal implant) 0.19 mg, for intravitreal injection. Prescribing Information. ANI Pharmaceuticals, Inc. Updated 2023. Accessed January 17, 2025. <https://hcp.iluvien.com/prescribing-information/>
2. Campochiaro PA, Brown DM, Pearson A, et al. Sustained delivery fluocinolone acetonide vitreous inserts provide benefit for at least 3 years in patients with diabetic macular edema. *Ophthalmology*. 2012;119(10):2125-2132.
3. Cunha-Vaz J, Ashton P, Iezzi R, et al; FAME Study Group. Sustained delivery fluocinolone acetonide vitreous implants: long-term benefit in patients with chronic diabetic macular edema. *Ophthalmology*. 2014;121(10):1892-903.
4. Eaton A, Koh SS, Jimenez J, Riemann CD. The USER study: a chart review of patients receiving a 0.2 µg/day fluocinolone acetonide implant for diabetic macular edema. *Ophthalmol Ther*. 2019;8(1):51-62.
5. Singer MA, Sheth V, Mansour SE, et al. Three-year safety and efficacy of the 0.19-mg fluocinolone acetonide intravitreal implant for diabetic macular edema: the PALADIN study. *Ophthalmology*. 2022;129(6):605-613.
6. Merrill PT, Holekamp N, Roth D, et al; PALADIN Study Group. The 0.19-mg fluocinolone acetonide intravitreal implant reduces treatment burden in diabetic macular edema [published online ahead of print, 2022 Oct 9]. *Am J Ophthalmol*. 2022;248:P16-23.
7. Khoramnia R, Peto T, Koch F, et al. Safety and effectiveness of the fluocinolone acetonide intravitreal implant (ILUVIEN): 3-year results from the European IRISS registry study. *Br J Ophthalmol*. 2023;107(10):1502-1508.
8. Gonzalez V. First real world analysis of safety in 0.19mg fluocinolone acetonide (FAC, ILUVIEN) implant treated eyes receiving supplemental ocular steroid injection for diabetic macular edema (DME). *Investig Ophthalmol Vis Sci*. 2019;60(9):2636.
9. Rehak M, Busch C, Unterlauff J, et al. Outcomes in diabetic macular edema switched directly or after a dexamethasone implant to a fluocinolone acetonide intravitreal implant following anti-VEGF treatment. *Acta Diabetologica*. 2020;57:469-478.